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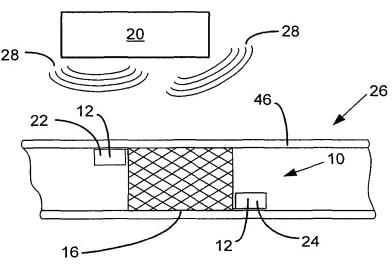
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(54) Title: MULTIPLE SENSOR DEPLOYMENT



(57) Abstract: A method of measuring pressure within the human body including implanting a pressure sensing assembly having a flexible structure and first and second sensor elements having self-contained power supplies coupled to the flexible structure. Periodic data collection events are performed to collect data from the sensor elements. A data collection event includes a request for data from a remote communication device, a transfer of sensor data to the remote communication device and a processing of the sensor data. The invention also includes a sensor assembly for implantation into a human body. The sensor assembly includes a first sensor having a self-contained power supply, a sensing element and an integral communication device capable of communicating with a remote communication device. The sensor

assembly also includes a second sensor and a flexible structure to which the first and second sensor are attached.

MULTIPLE SENSOR DEPLOYMENT

TECHNICAL FIELD

[0001] The present invention relates to sensors that are implantable within the human body. More specifically, the invention relates to devices and methods for implanting multiple sensors within the human body.

BACKGROUND

[0002] Medical sensors can be implanted into the human body to retrieve diagnostic data regarding certain bodily functions. For example, pressure sensors located within the vascular system of the body can measure blood pressure at various locations within the body. FIG. 1 illustrates a representative sensor assembly 2 having a sensor 4 and a compressible retention member 6 positioned within a blood vessel 8. The sensor 4 is a self-contained device, having its own power supply and communication circuitry for communicating data to a remote device. Sensors of this type can be implanted into the body by inserting a catheter into the body and moving the catheter through the cardio-vascular system until the end of the catheter is positioned at the desired implant location. The sensor can then be fed through the catheter and positioned within the appropriate blood vessel.

Due to the nature of the human body, portions of the vascular system through which the catheter is navigated can have relatively acute radii, and thus the catheter may be required to make one or more turns within the body before reaching the desired implant location. Thus, any sensor that is fed through the body must be small enough to negotiate any turns in the catheter when it is positioned within the body. This size limitation impacts the size of the power supply contained within the sensor and correspondingly, impacts the life of the power supply and thus the amount of time that a sensor can function within the body. For example, a sensor may have a power supply with a rated life of 10 years under normal use, including periodic recharging. It is not desirable to replace sensors of this type within the

body. Therefore, it is desirable to be able to extend the length of time that diagnostic data can be retrieved at a given site without requiring replacement of sensors. What is needed, then, is a way to measure diagnostic data at a given site for longer periods of time, given the constraints of size on diagnostic sensors.

SUMMARY

The invention is directed toward a method of measuring pressure within the human body. The method includes implanting a pressure sensing assembly into a human body. The sensing assembly includes a flexible structure capable of expanding when implanted and first and second sensor members each having self contained power supplies. The method includes performing periodic data collection events, including collecting a sensor data packet from at least one of the first and second members.

The invention is also directed toward a sensor assembly for implantation into a human body. The sensor assembly includes a flexible structure capable of expanding when implanted within the human body and first and second sensor members. The first sensor member includes a self-contained power supply, a sensing element and an integral communication device capable of communicating with a remote communication device. The sensor assembly is, in one aspect, part of a pressure sensing system implanted within a human body. The pressure sensing system includes a remote communication device implanted within the human body. In one aspect of the invention, the remote communication device is a pulse generator. The remote communication device is capable of broadcasting messages to the sensors. Broadcast messages include address data that is recognized by the intended sensor members.

[0006] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments

of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a cross-sectional fragmentary view of a cavity within the human body with a prior art implantable sensor assembly positioned therein.

[0008] FIG. 2 illustrates an implantable multi-sensor assembly that can be used in relation to embodiments of the present invention.

[0009] FIG. 3 is a functional block diagram of a sensor element of the multisensor assembly of FIG. 2.

[0010] FIG. 4 is a cross-sectional view of the implantable multi-sensor assembly of FIG. 2 positioned at a radius within an insertion tool.

[0011] FIG. 5 is a flow diagram of a method of communication between the sensors of the multi-sensor assembly and a remote communication device according to one embodiment of the invention.

[0012] FIG. 6 is a flow diagram of a method of communication between the sensors of the multi-sensor assembly and a remote communication device according to another embodiment of the invention.

[0013] FIG. 7 is a flow diagram of a method of communication between the sensors of the multi-sensor assembly and a remote communication device according to yet another embodiment of the invention.

[0014] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

FIG. 2 illustrates a sensor assembly 10 having a plurality of sensor [0015] members 12 each coupled to a compressible retention device 16 implanted into a blood vessel 26 of a human body according to one embodiment of the invention. The sensor assembly 10, as described below, includes two or more sensor members 12 and is capable of being implanted within the cardiovascular system of the human body to measure blood pressure at the implant location. The sensor assembly 10 is shown positioned within a blood vessel 26 within a human body. The compressible retention device 16 is expanded to contact the inner surface 46 of the blood vessel 26 to retain the sensor assembly 10 in its proper position. The compressible retention device 16 can be a stent, a strut, or other similar devices. Each of the sensor members 12 are coupled to the compressible retention device 16 by welding the sensor members 12 to the retention device 16 or by using other known coupling structures. The sensor assembly 10 is shown having two sensor members 12, although the sensor assembly can have any number of additional sensor members without departing from the scope of the invention. For example, the sensor assembly 10 could have a third sensor member (not shown) coupled to the compressible retention device 16.

[0016] When the sensor assembly 10 is implanted within the human body as shown in FIG. 2, the sensors 12 are capable of communicating with a remote communication device 20 via the communication link 28. The remote communication device 20, in one embodiment, is a pulse generator implanted within the human body. Alternatively, the remote communication device 20 can be any other device, either implanted within or externally located from the human body. In one embodiment, the communication link 28 between the sensors 12 and the communication device 20 is established using wireless acoustic communication. Alternatively, the communication link 28 can be established through inductive, radio frequency, or other communication technologies.

Sensors 12 of the sensor assembly 10 are further identified as a first sensor member 22 and a second sensor member 24. For the purposes of this specification, the sensor members 12 of the sensor assembly 10 are referred to collectively or generically as sensor members 12, but individually and specifically as a first sensor member 22 and a second sensor member 24. FIG. 3 is a block diagram of the sensor member 12. The sensor member 12 includes a rechargeable power supply 30, a sensing element 32, a memory 38, including address data 34, a communication element 36, and a controller 40. The communication element 36 includes appropriate structure to communicate with the remote communication device 20 (FIG. 2) and can include one or more communication technologies of the types listed above and/or others. The power supply 30 can be a battery.

The memory 38 can be any type of memory known in the art. By way of example, but not limitation, the memory 38 can include random access memory (RAM) or read only memory (ROM). The memory 38 could include electrically erasable programmable ROM (EEPROM). Other types of memory may be known in the art that may be suitable for particular implementations. The controller 40 could be, without limitation, a microcontroller, a microprocessor, a digital signal processor, or an application specific integrated circuit (ASIC). The controller 40 may have registers for temporary storage of data or executable instructions, which may be read from memory 38.

The address data 34 provides identification within the sensor member 12 to allow the sensor member 12 to determine whether the sensor member 12 is the intended recipient of a messages or data. Messages from the communication device 20 may be broadcast messages or targeted to particular sensor members. Targeted messages sent from the remote communication device 20 include an address associated with the intended sensor member 12. Each sensor member 12 processes messages that have an address that corresponds to its unique address. Thus, the remote communication device 20 is capable of directing a message to one or all of the sensor members 12. In one embodiment, the address data 34 is stored

in reprogrammable or read only digital memory. It is anticipated that the first sensor member 22 and the second sensor member 24 can have the same or similar construction. However, the first sensor member 22 and the second sensor member 24 can include some differences and other features without departing from the scope of the invention.

The sensor element 32 detects a physiologic parameter, such as, but not limited to, pressure, and emits a signal corresponding to the detected parameter. In this respect, the sensor element 32 may be piezo or capacitive in nature, or any other appropriate technology for sensing a physiologic parameter of interest. Although embodiments described herein relate primarily to sensing of blood pressure, it will be understood by those of skill in the art that other types of physiologic parameters may be sensed, depending on the particular application. The sensor member 12 is typically housed in a housing composed of a biocompatible material to facilitate implantation in the human body.

FIG. 4 illustrates a portion of an insertion tool 42 used to implant the sensor assembly 10 according to one embodiment of the invention. The insertion tool 42 can be a flexible catheter that is inserted into the vascular system of the human body and fed through to a desired implantation location within the human body. Once the insertion tool 42 is properly located within the human body, the sensor assembly 10 can be fed through the insertion tool 42 to the desired implantation location. When the sensor assembly 10 is loaded into the insertion tool 42, the compressible retention device 16 is compressed so that the sensor assembly 10 is capable of fitting within the insertion tool 42. As is shown in FIG. 4, the compressible retention member 16 is flexible enough to conform to a radius 44 and thus both of the sensor members 12 are able to pass though the radius. Once the sensor assembly 10 is fed through the insertion tool 42, it is located in the blood vessel 26 (FIG. 2). The compressible retention member 16 expands to engage the inner surface 46 of the blood vessel 26 to secure the sensor assembly 10 into

position. Alternatively, the sensor assembly can be implanted in other portions of the human body, including, but not limited to, the esophagus and the air canal.

FIG. 5 is a functional flowchart 100 that illustrates a method of [0022] communicating sensor data packets between the remote communication device 20 (FIG. 2) and the sensor members 12 (FIG. 2) according to one embodiment of the invention. The remote communication device 20 and the sensor members 12 have a master/slave relationship such that the sensor members 12 rely on a communication from the remote communication device 20 before they perform any data collection and/or transmission. Therefore, it is the remote communication device 20 that determines what and when steps are taken in the communication method illustrated in flowchart 100. Prior to any request from the remote communication device 20, the sensor members 12 are in a power save state. It is to be understood that the description of the data collection method below describes the functional aspects of the method and that numerous implementations can be used to achieve the described functions. For example, communication protocols can be used to define the structure of messages sent between the remote communication device 20 and the sensor members 12. One particular implementation of the communication protocol between the remote communication device 20 and sensor members 12 is described in detail in related application XX/XXX,XXX, which was filed on the same day as this application and claims priority to U.S. Provisional Patent Application Serial No. 60/820,059, both of which are incorporated herein by reference in their entireties for all purposes.

Referring to block 102 of flowchart 100, the remote communication device 20 seeks to acquire a sensor data packet from the first sensor member 22. The remote communication device 20 initiates communication with the first sensor member 22 either at a predetermined time or in response to a request from an external communication device (not shown). The remote communication device 20 broadcasts a sensor data request message requesting sensor data from the first sensor member 22 (FIG. 2). The remote communication device 20 then waits a

predetermined amount of time for the first sensor member 22 to respond. The data request message can request a single sensor data point, multiple sensor data points, or a continuous stream of data for a given period of time.

[0024] When a sensor data request message requesting sensor data from the first sensor member 22 is broadcast, all of the sensor members 12 receive the message and enter an identification state. When the sensor member(s) 12 is in an initialization state, the sensor member(s) 12 processes incoming communication data to determine whether the message is intended for that particular sensor. The sensor data request message from the remote communication device 20 includes an address. Each of the sensor members 12 compares the address in the sensor data request message to determine whether the address corresponds to that sensor member's address. If the sensor member(s) 12 determines that the addresses don't match, the sensor member(s) 12 ignores the message and returns to the power save state.

The sensor data request message of block 102 includes an address that corresponds to the unique address data 38 of the first sensor member 22. The first sensor member 22, recognizing that the address of the sensor data request message matches its unique address data 38 then enters into an active state in which the first sensor member 22 collects sensor data and transmits a sensor data packet back to the remote communication device 20. The sensor data packet, in one embodiment includes sensed data, such as pressure. In addition, the sensor data packet includes a power supply value that describes the charge level of its power supply. Once the first sensor member 22 has transmitted its data to the remote communication device 20, it returns to a power save state.

[0026] Referring to block 104, after sending the sensor data request message and waiting a predetermined length of time, if the remote communication device 20 has not received a sensor data packet from the first sensor member 22, the remote communication device 20 will request information from the second sensor member 24, as is illustrated in block 120 and described below. Before the remote

communication device 20 sends a sensor data request message to the second sensor member 24, the remote communication device 20 may attempt more than once to collect information from the first sensor member 22. If, however, the remote communication device 20 does receive data from the first sensor member 22, the remote communication device 20 processes the sensor data packet received from the first sensor member 22 as illustrated in block 106 of flowchart 100.

The step of processing the sensor data packet can include storing the [0027] sensed data and/or power supply value, communicating the sensor data and/or power supply value to another remote device (not shown), using the sensor data and/or power supply value in calculations and/or algorithms, or any combination of the above. As shown in block 108, the remote communication device 20 next determines whether the first sensor member 22 has adequate charge left in its power supply 30 (Fig.3). The power supply value is compared against a charge threshold value to determine whether the first sensor member 22 has sufficient charge remaining to continue collecting sensor data and to transmit it to the remote communication device 20. If the power supply value is greater than the threshold value, the first sensor member 22 has adequate charge remaining and the remote communication device waits (represented as a delay in block 110) either for a predetermined amount of time or for a request from another remote device (not shown) to go to block 102 and repeat the data collection cycle. If, however, the power supply value is lower than the threshold value, the first sensor member 22 has an inadequate charge left in its power supply, and the remote communication device 20 waits (represented as a delay in block 128) for either a predetermined amount of time or for an external request to go to request data from the second sensor member 24.

[0028] Block 120 represents the request for sensor data from the second sensor member 24. The remote communication device 20 sends a sensor data request message having an address that corresponds to the unique address 38 of the second sensor member 24. The remote communication device 20 then waits for

the second sensor member 24 to respond. If the second sensor member 24 receives the sensor data request message, it enters an active state, collects sensor data and the power supply value, transmits a data packet back to the remote communication device 20, and returns to a power save state.

Referring to block 122, after sending the sensor data request message [0029] and waiting a predetermined length of time, if the remote communication device 20 has not received a sensor data packet from the second sensor member 24, the remote communication device 20 will request information from the first sensor member 22, as is illustrated in block 102 and described above. Before the remote communication device 20 sends a sensor data request message to the first sensor member 22, the remote communication device 20 may attempt more than once to collect a sensor data packet from the second sensor member 24. It should be noted that the remote communication device 20 requests sensor data from the second sensor member 24 only after either not receiving a response to a data request from the first sensor member 22 or due to a low charge condition on the first sensor member 22. However, because the power supply is rechargeable, it is entirely possible that the first sensor member 22 has been recharged and will be able to respond to a request for sensor data despite being unable to do so previously. If, however, the remote communication device 20 receives a sensor data packet from the second sensor member 24, the remote communication device processes the data packet as illustrated in block 124. The sensed data received from the second sensor member 24 is processed in a similar manner to that described above with respect to the first sensor member 22.

[0030] As illustrated in block 126, the remote communication device 20 next determines whether the second sensor member 24 has adequate charge left in its power supply 30. The power supply value of the second sensor member 24 is compared against the charge threshold value. If the power supply value is greater than the threshold value, the second sensor member 24 has adequate charge left in its power supply 30 and the remote communication device 20 waits (represented as

a delay in block 128) either a predetermined amount of time, or for an external request to prompt the remote communication device to request data from the second sensor member 24 (as illustrated in block 120).

If, however, the power supply value is lower than the threshold value, [0031] the second sensor member 24 has an inadequate charge left in its power supply and the remote communication device 20 waits (represented as a delay in block 110) for a prompt to request sensor data from the first sensor member 22 (as illustrated in block 102). Alternatively, the remote communication device 20 may from time to time jump from block 128 to block 102 by issuing a sensor data request message with an address corresponding to the unique address 38 of the first sensor member 22 in attempt to request data from the first sensor member 22 even though the second sensor member 24 is working properly and has sufficient charge (not shown in flowchart 100). While flowchart 100 details the interaction between the remote communication device 20 and a sensor assembly 10 having two sensor members 12, other embodiments can include any number of sensor members 12. In those instances, the remote communication device 20 can move from one sensor to the next to get readings from a sensor with adequate charge in a way similar to that described here. Further, while flowchart 100 and the description above detail the transmission of a single sensor data packet transmission per sensor data request, a single data request could alternatively request a plurality of sensor data packets to provide readings over a period of time.

[0032] FIG. 6 is a functional flowchart 200 that illustrates a method of communication of sensor data between the remote communication device 20 and the sensor members 12 (shown in FIG. 2) according to another embodiment of the invention. In this embodiment, the remote communication device 20 alternates data collection between the first sensor member 22 and the second sensor member 24 (and any additional sensors) rather than collecting data from just one sensor until that sensor fails to respond or signals a low charge.

geeks to acquire sensor data from the first sensor member 22. The remote communication device 20 initiates communication with the first sensor member 22 by broadcasting a data request message having an address corresponding to the unique address 38 of the first sensor member 22 as is described above with respect to block 102 of flowchart 100. The first sensor member 22 responds as described above by providing a sensor data packet to the remote communication device 20 and then returns to a power save state.

Referring to block 204, after sending the sensor data request message and waiting a predetermined length of time, if the remote communication device 20 has not received a sensor data packet from the first sensor member 22, the remote communication device will request information from the second sensor member 24, as is illustrated in block 220 and described below. As in step 104 of flowchart 100, if the first sensor member 22 has not responded in a timely manner, the remote communication device 20 may attempt more than one request for information before attempting to communicate with the second sensor member 24.

[0035] If the remote communication device 20 receives timely data from the first sensor member 22, the remote communication device 20 processes the data at block 206. The step of processing the sensor data packet can include storing the sensed data and/or power supply value, communicating the sensed data and/or power supply value to another remote device (not shown), using the sensed data and/or power supply value in calculations and/or algorithms, or any combination of the above. After processing the sensor data packet, the remote communication device 20 waits, as represented in block 208, either for a predetermined amount of time or for a request from another remote device (not shown) to request data from the second sensor member 24.

[0036] Referring to block 220, the remote communication device 20 broadcasts a message requesting a sensor data packet from the second sensor member 24 similar to the procedure described above related to step 120. The first

sensor member 22 responds by providing a sensor data packet to the remote communication device 20 as described above and then returns to a power save state.

Referring to block 222, after sending the sensor data request message [0037] and waiting a predetermined length of time, if the remote communication device 20 has not received a sensor data packet from the second sensor member 24, the remote communication device will request information from the first sensor member 22, as is illustrated in block 202 and described above. Before the remote communication device 20 sends a sensor data request message to the first sensor member 22, the remote communication device 20 may attempt more than once to collect a sensor data packet from the second sensor member 24. If neither the first sensor member 22, nor the second sensor member 24 is responding, the remote communication device 20 will not continuously shift between requesting sensor data packets from the first and second sensor members, 22, 24, but will wait a predetermined time before attempting to establish communication with the first sensor member 22 after it has been determined that neither sensor is responding to data requests. If, however, the remote communication device 20 receives data from the second sensor member 24, the remote communication device processes the data as illustrated in block 224. The data received from the second sensor member 24 is processed in a similar manner to that described above with respect to the first sensor member 22. After processing data received from the second sensor member 24, the remote communication device 20 waits, as represented by a delay in block 226, either for a predetermined amount of time or for a request from another remote device (not shown) to move to step 202 and request data from the first sensor member 22.

[0038] FIG. 7 is a functional flowchart 300 of a data collection method between the remote communication device 20 (FIG. 2) and the sensor members 12 (FIG. 2) according to another embodiment of the invention. In this embodiment, the remote communication device 20 requests a sensor data packet from each of the

sensor members 12 simultaneously. A sensor data request can request data in different forms. For example, the sensor data request can specify that each of the sensors return a specified number of sensor data packets or the sensor members 12 return data values in a continuous stream of data for a given period of time. In response, the sensor members 12 transmit messages to the remote communications device 20. In some embodiments, sensor data values are transmitted sequentially in a specified order continuously from the time the remote communications device requests the sensor data until all of the data has been transmitted. In these and other embodiments, the data collection method may be performed in response to an external data request, or alternatively, it may be performed periodically.

Referring to block 302 of flowchart 300, prior to any communication between the remote communication device 20 and the sensor members 12, the sensor members are in a power save state. The remote communication device 20 requests a sensor data packet from each of the plurality of sensor members 12 by broadcasting a request for sensor data message including an address that corresponds to the global address 40 of each of the sensor members 12. In one embodiment, the message sent to request the sensor data from the sensor members 12 by the remote communication device 20 prescribes the order and for how long the sensor members 12 are to return information. For each sensor member 12, the remote communication device 20, in one embodiment, indicates how long after the request for sensor data a particular sensor should wait before making its first transmission, the delay between each subsequent transmission, and for how long the sensors are to return data after the request for sensor data.

[0040] As an example, a human body has two implanted sensor members 12 and it is desired that the two sensor members 12 transmit information for 10 seconds. Each sensor data packet transmission lasts 250 milliseconds. The first sensor member 22 will be instructed or will have stored within it to begin transmitting information at time t=0 and begin a transmission every 500 milliseconds. The

second sensor member 24 will be instructed to begin transmitting information at time t=250 milliseconds and begin a transmission every 500 milliseconds thereafter. The request for data message may request continuous data for 10 seconds. Upon receipt of the request for data message, the first sensor member 22 begins transmission of its first sensor data packet at t=0 seconds. The second sensor member 24 begins transmission at t=250 milliseconds. The sensor members 12 then alternate sending packets every 250 milliseconds for 10 seconds so that the data returned from the sensor members 12 is interleaved. By staggering the transmissions, data collisions between two sensors attempting to transmit simultaneously are avoided. It should be understood that time t=0 may be some period of time after the receipt of the data message to allow time for the sensor to collect data.

The specific time intervals in the example above are not intended to be limiting, as any time interval may be used, depending upon the amount of data to be collected, the number of sensors implanted in the body, and the length of time required to transmit each message from one of the sensor members 12 to the remote communication device 20.

Alternatively, the remote communication device 20 can provide each sensor member 12 with specific information regarding its order prior to the request for data message sent to each of the sensor members individually, by transmitting a series of messages each of which has an address that corresponds to one of the unique addresses 38 (FIG. 3) of the sensor members 12. The information provided by the remote communication device 20 to each sensor member 12 includes when to begin transmitting packets after receiving the broadcast message requesting sensor data, how much time the sensor member 12 should wait before transmitting that information and how often to transmit the packets. Alternatively still, each sensor members 12 includes specific information stored within the sensor member regarding when to begin transmitting messages after receiving the broadcast message requesting sensor data packets and how often to transmit the messages,

therefore not requiring any communication from the remote communication device 20 to set the order of transmission. Once communication is initiated by the remote communication device 20, the sensor members 12 are in an identification state. After receiving the request for sensor data message, the sensor members 12 are in an active state.

Referring to block 304, the sensor members 12 transmit sensor data to the remote communication device 20 using the interleaving pattern of staggering data transmissions described above. The information is sent for the period of time defined in the request for data. Once the sensor data has been transmitted to the remote communication device 20, the sensor members 12 return to a power save state. Referring to block 306, the data sent by the sensor members 12 and received by the remote communication device 20 is processed by the remote communication device 20. Processing data can include storing the sensor packet data within the remote communication device 20, communicating the sensor data to another remote device (not shown in FIG. 2), using the sensor packet data in calculations and/or algorithms, or any combination of the above.

example, in a pulmonary artery, given that the distance between the sensor members 12 is known, it is possible to calculate mass blood flow through the artery using the data from the pulses over time. A particular method for calculating blood flow rate is described in U.S. Patent 6,277,078, issued August 21, 2001, and entitled "System and Method for Monitoring a Parameter Associated With the Performance of a Heart," which is incorporated herein by reference for all purposes. In one embodiment, the data collection method illustrated in flowchart 300 and described above is initiated in response to an external request. Alternatively, the data collection method is performed periodically and is initiated after a specified period of time. While the remote communication device 20 may collect data periodically to measure mass blood flow, it need not use the data collection method described here exclusively. For example, the remote communication device 20 can use the method

described in either the flowchart 100 or flowchart 200 primarily and intersperse the method described in flowchart 300 every 100 times data is collected or any other frequency.

In view of the foregoing, various embodiments are advantageous from several respects. For example, although optionally rechargeable, repeated recharging events and power drainage the power supplies can degrade and eventually be unable to maintain a charge. By having two or more sensors implanted in close proximity to one another, either of the sensors can be used to take readings, thereby reducing the overall usage of each sensor, and reducing the need for recharging events and, as a result, extending the life of sensors.

[0046] As another example, with the sensor assembly 10 according to various embodiments, it is possible to get sensors positioned more closely together where it would otherwise be difficult to implant two sensors close together without disturbing one or both of the sensors.

[0047] As another example, because the sensors of the assembly 10 are spaced apart at a known fixed distance according to some embodiments, it is possible to make calculations of mass blood flow by measuring the pulses as they pass each of the sensors as described above.

[0048] As a final example, because embodiments include multiple sensors (e.g., two), a redundant backup optionally exists for safety purposes.

Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

CLAIMS

What is claimed is:

1. A method of measuring blood pressure within a human body, comprising:

implanting a pressure sensing assembly into a vessel near the heart in the human body, the sensor assembly including a flexible structure capable of expanding when implanted, a first sensor member having a self contained electric power supply coupled to the flexible structure, and a second sensor member having a self contained electric power supply coupled to the flexible structure; and

performing periodic data collection events, including collecting a sensor data packet from at least one of the first sensor member and the second sensor member.

- 2. The method of claim 1, wherein the step of performing a data collection event includes collecting a plurality of sensor data packets from one of the first sensor member and the second sensor member.
- 3. The method of claim 1, wherein the step of performing a data collection event includes collecting a plurality of sensor data packets from each of the first sensor member and the second sensor member.
- 4. The method of claim 3, wherein the step of performing a data collection event includes collecting a plurality of sensor data packets interleaved from the first sensor member and the second sensor member.

5. The method of claim 1, wherein the step of performing periodic data collection events includes performing alternating periodic events of collecting data from the first sensor member and collecting data from the second sensor member.

- 6. The method of claim 1, wherein the step of performing periodic data collection events includes
 - providing a request for data from a remote communication device to the first sensor element;
 - transferring a sensor data packet from the first sensor member to the remote communication device in response to the request for data; and
 - processing the sensor data packet transferred to the remote communication device from the pressure sensing assembly in response to the request for data.
- 7. The method of claim 6, wherein the step of providing a request for data from a remote communication device to the first sensor member includes broadcasting a message and wherein the message includes address information recognized by the first sensor member.
- 8. The method of claim 6, wherein the step of transferring a sensor data packet from the first sensor member includes transferring a power supply value representing the charge level of the self-contained power supply, the step of processing the sensor data includes comparing the power supply value against a threshold value, and the step of collecting data from the second sensor element is not performed until the charge value of the self-contained power supply of the first sensor member is lower than the threshold level.

9. The method of claim 1, wherein the step of implanting a pressure sensing assembly includes:

inserting a first end of a hollow flexible insertion tool into the human body and feeding the insertion tool into the body so that the first end is positioned adjacent to a desired implantation site;

inserting the pressure sensing assembly into a second end of the insertion tool;

urging the pressure sensing assembly through the insertion tool until the assembly is seated at the desired implantation site; and removing the insertion tool.

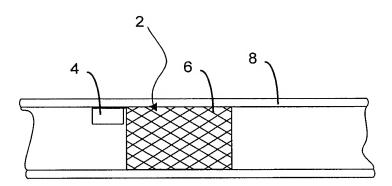
- 10. A pressure sensing system comprising:
 - a pressure sensing assembly for implantation into a human body, comprising:
 - a flexible structure capable of expanding when implanted within the human body;
 - a first pressure sensor member coupled to the flexible structure, including:
 - a self-contained power supply;
 - a sensing element; and
 - an integral communication device capable of communicating with a remote communication device; and

a second pressure sensor member coupled to the flexible structure.

- 11. The sensor assembly of claim 10, wherein the flexible structure is a stent.
- 12. The sensor assembly of claim 10, wherein the flexible structure has a first end and a second end, and wherein the first sensor member is coupled to the first end.
- 13. The sensor assembly of claim 12, wherein the second sensor member is coupled to the second end of the flexible structure.
- 14. The pressure sensing system of claim 10, further comprising a remote communication device implanted within the human body.
- 15. The pressure sensing system of claim 14, wherein the remote communication device is a pulse generator.
- 16. The pressure sensing system of claim 14, wherein the remote communication device is capable of broadcasting messages having address data and wherein the first sensor element includes address data and is capable of recognizing messages broadcast from the remote communication device having corresponding address data.
- A sensor assembly for implantation into a human body, comprising:
 a flexible structure capable of expanding when implanted within a vessel in the human body;

a first pressure sensor means coupled to the flexible structure; and a second pressure sensor means coupled to the flexible structure.

- 18. The sensor assembly of claim 17, wherein the flexible structure is a stent.
- 19. The sensor assembly of claim 17, wherein the flexible structure defines first and second opposing ends and the first pressure sensor means is coupled to the first end and the second pressure sensor means is secured to the second end of the flexible structure.
- 20. The sensor assembly of claim 17, wherein the sensor assembly is adapted to be implanted within a bodily vessel through a catheter.



PRIOR ART FIG. 1

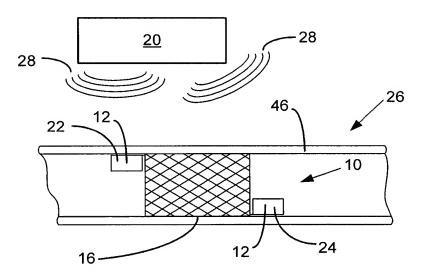


FIG. 2



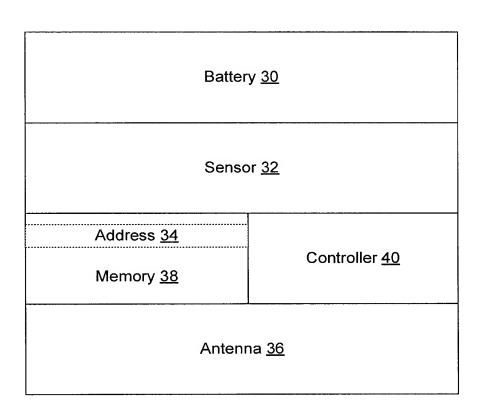


FIG. 3

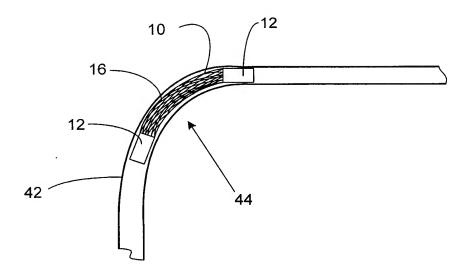
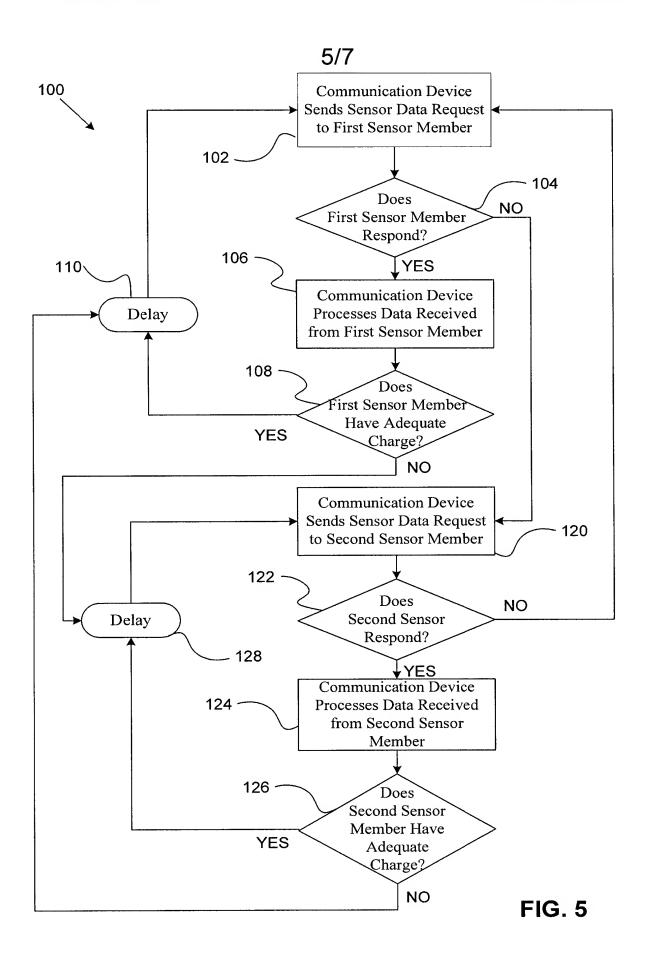


FIG. 4



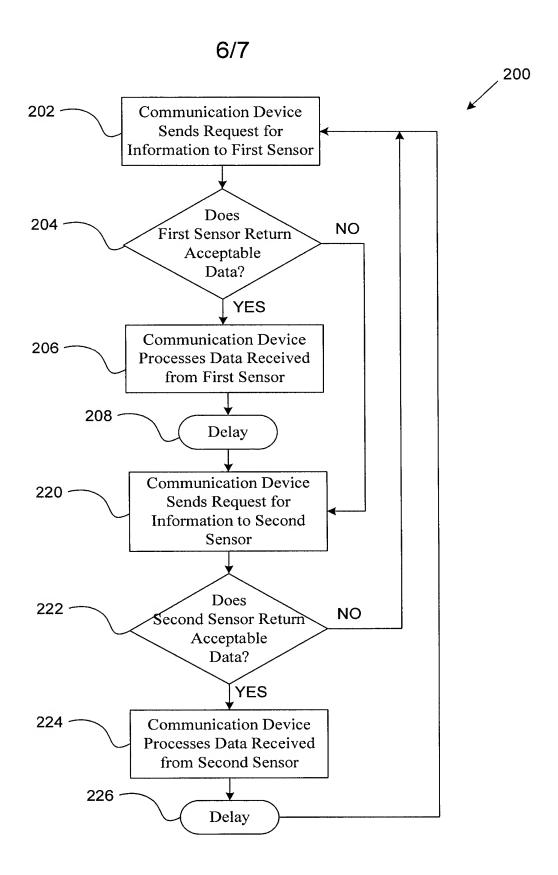


FIG. 6

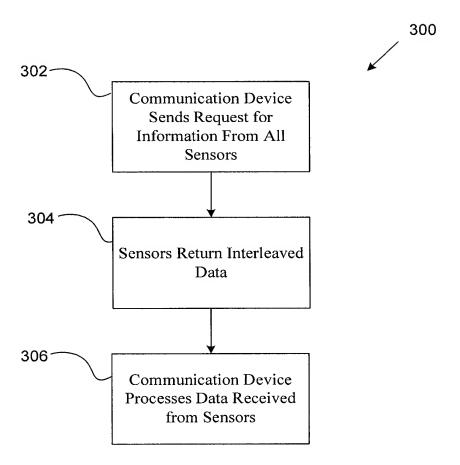


FIG. 7

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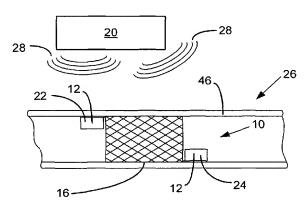
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[Continued on next page]

(54) Title: MULTIPLE SENSOR DEPLOYMENT



(57) Abstract: A method of measuring pressure within the human body including implanting a pressure sensing assembly having a flexible structure and first and second sensor elements having self-contained power supplies coupled to the flexible structure. Periodic data collection events are performed to collect data from the sensor elements. A data collection event includes a request for data from a remote communication device, a transfer of sensor data to the remote communication device and a processing of the sensor data. The invention also includes a sensor assembly for implantation into a human body. The sensor assembly includes a first sensor having a self-contained power supply, a sensing element and an integral communication device capable of communicating with a remote communication device. The sensor assembly also includes a second sensor and a flexible structure to which the first and second sensor are attached.



- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/0215 A61B5/00 A61B5/07 ADD. A61F2/06 According to International Patent Classification (IPC) onto both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61N A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the International search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Citation of document, with Indication, where appropriate, of the relevant passages Category* US 6 277 078 B1 (PORAT YARIV [IL] ET AL) 10-13, Х 17-20 21 August 2001 (2001-08-21) 14-16 Y column 10, line 43 - column 13, line 3 figures 10-14 χ US 2002/183628 A1 (REICH SANFORD [US] ET 10,12,13 AL) 5 December 2002 (2002-12-05) paragraph [0033] - paragraph [0034] paragraphs [0055], [0061] paragraph [0065] - paragraph [0067] paragraph [0076] - paragraph [0078] figures 1-9 -/--Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: 'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the International 'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-ments, such combination being obvious to a person skilled in the art. document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 20/02/2008 11 February 2008 Name and malling address of the ISA/ Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Görlach, Tobias Fax: (+31~70) 340-3016

INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.					
Υ	US 2006/031378 A1 (VALLAPUREDDY VINEEL [US] ET AL) 9 February 2006 (2006-02-09) paragraph [0042] - paragraph [0043] paragraph [0048] - paragraph [0049] paragraph [0087] - paragraph [0088] figures 1,2A,2B,9	14-16					
A	US 6 141 588 A (COX TIMOTHY J [US] ET AL) 31 October 2000 (2000-10-31) column 7, line 33 - column 14, line 12 figures 2-6	10-20					
A	US 2005/080346 A1 (GIANCHANDANI YOGESH B [US] ET AL) 14 April 2005 (2005-04-14) paragraph [0046] - paragraph [0055] figures 3-5	10-20					
A	US 2003/158584 A1 (CATES ADAM W [US] ET AL) 21 August 2003 (2003-08-21) paragraph [0157] - paragraph [0169] figures 2,5,25-27	10-20					
A	US 2004/199238 A1 (BROWN PETER S [US] ET AL) 7 October 2004 (2004-10-07) paragraph [0043] - paragraph [0048] figures 2,3	10-20					

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)							
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:							
1. X Claims Nos.: 1-9 because they relate to subject matter not required to be searched by this Authority, namely: Article 17(2)(a)(i) and Rule 39.1(iv) PCT - Method for treating of the human (or animal) body by surgery.							
Claims Nos.: because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:							
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).							
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)							
This International Searching Authority found multiple inventions in this International application, as follows:							
1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.							
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.							
As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:							
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:							
The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee. The additional search fees were accompanied by the applicant's protest but the applicable protest							
fee was not paid within the time limit specified in the invitation.							
No protest accompanied the payment of additional search fees.							

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2007/074020

Patent document cited in search report		Publication date	Patent family Publication member(s) date	
US 6277078	В1	21-08-2001	AU 1297701 A 30-05-200 WO 0136014 A2 25-05-200	_
US 2002183628	A1	05-12-2002	NONE	-
US 2006031378	A1	09-02-2006	EP 1784123 A1 16-05-200 WO 2006017615 A1 16-02-200	
US 6141588	A	31-10-2000	NONE	-
US 2005080346	A1	14-04-2005	NONE	-
US 2003158584	A1	21-08-2003	NONE	_
US 2004199238	A1	07-10-2004	EP 1511443 A1 09-03-2009 W0 03103539 A1 18-12-2009 US 7261733 B1 28-08-2009 US 2006200220 A1 07-09-2009 US 2005107866 A1 19-05-2009	3 7 6